NOV 0 7 2001

510(k) Summary of Safety & Effectiveness

K012700

Submitter

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

Contact

Mr. Mike Sammon, Ph.D.
Director, Research and Development
(863) 683-8680, extension 228
(801) 327-3339 (facsimile)
mikes@safe-reuse.com

Date

August 10, 2001

Device

- Trade Names: Vanguard Reprocessed Endoscopic Instruments
  - ⇒ Ethicon Endo-Surgery ENDOPATH® Endoscopic Instruments with monopolar cautery
  - ⇒ AutoSuture® ENDO DISSECT®, ENDO SHEARS®, ENDO SHEARS® LONG, and ENDO MINI-SHEARS® Endoscopic Instruments with unipolar cautery
- Common Name: Endoscopic or laparoscopic surgical instrument
- Classification: 21 CFR 878.4400 – Electrosurgical cutting and coagulation device and accessories – Class II
- Product Code GEI

Predicate Devices

Respective Ethicon Endo-Surgery ENDOPATH® and AutoSuture® ENDO DISSECT®, ENDO SHEARS®, ENDO SHEARS® LONG, and ENDO MINI-SHEARS® legally marketed endoscopic instruments under various 510(k) premarket notifications.

Indications for Use

An endoscopic instrument is used during minimally invasive surgery in conjunction with an appropriately sized trocar and a compatible electrosurgical unit for grasping, mobilization, dissection, transection and/or cauterization of tissue.

Continued on next page

510(k) Summary of Safety & Effectiveness, Continued

Contra-indications

This device is not intended for:

- contraceptive coagulation of fallopian tissue, nor
- applications where minimally invasive surgery is contraindicated.

Device Description

The endoscopic instrument is used for grasping, dissection and cauterization in endoscopic general surgery. It is designed for insertion through an appropriately sized trocar/cannula. The instrument scissors or jaws are opened and closed using ring handles. A 3 mm pin at the distal end of the device connects to a compatible electrosurgical unit for electrocautery. The device's insulated shaft can be rotated 360° in either direction using a knob on the handle.

Vanguard receives previously used endoscopic instruments from healthcare facilities; cleans, refurbishes (replaces insulation), inspects, tests, repackages and sterilizes the devices; and returns them to the healthcare facility.

Technological Characteristics

The Vanguard reprocessed endoscopic instruments are essentially identical to the currently marketed OEM wands. No changes are made to the currently marketed device's specifications (except for the insulation material) and they possess the same technological characteristics. Biocompatibility and performance/functional testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use.

Test Data

Cleaning, sterilization and packaging validations, functional/performance, and biocompatibility testing demonstrate that the reprocessed devices perform as intended and are safe and effective.

Conclusion

Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard reprocessed endoscopic instruments are substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 7 2001

Mr. Mike Sammon, Ph.D.
Director, Research and Development
Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, Florida 33815

Re: K012700
Trade/Device Name: Vanguard Reprocessed Endoscopic Instruments
Regulation Number: 21 CFR 878.4400 and 876.1500
Regulation Name: Electrosurgical Cutting and Coagulation Devices and accessories and Endoscope and accessories
Regulatory Class: Class II
Product Code: GEI and GCJ
Dated: August 10, 2001
Received: August 13, 2001

Dear Mr. Sammon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MD

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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K012700

Indications for Use

510(k) Number: K012700

Device Name: Vanguard Reprocessed Endoscopic Instruments

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Walker

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012700